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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,311	03/02/2004	Alexander Gad	60807-AA-PCT-US/JPW/GJG/D	4992

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John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/792,311	GAD ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *123-164* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *123-125,127,128,133-136,138,139,144-147,149,150,155-157,159 and 160* is/are rejected.

7)☒ Claim(s) *126,129-132,137,140-143,148,151-154,158 and 161-164* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/25/04; 3/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 123-164 are pending.

2. Applicant's election with traverse of Group 1, Claims 123-144 drawn to drawn to a process for obtaining a pharmaceutical product containing an aqueous mixture of polypeptides, each of which consists essentially of alanine, glutamic acid, tyrosine and lysine, filed 10/8/04, is acknowledged. The traversal is on the grounds that claims 123-164 do not fall into the examples of independent inventions of claims 145-164 are provided in MPEP §806.04. The process of claim 123 and the process of claim 134 each recites the steps of the process of claim 145 and therefore, claims 123-144 are not independent from claims 145-164. Further, examination of any of the claims 123-164 will require the examination of a process for determining the average molecular weight of an aqueous mixture of polypeptides. Therefore, examination of claims 145-164 will place no additional burden on the examiner than the examination of elected claims 123-144. Upon reconsideration, Group I and II now (claims 123-164) have been rejoined is still deemed proper and is therefore made FINAL.

3. Claims 123-164, drawn to a process for obtaining a pharmaceutical product containing an aqueous mixture of polypeptides, each of which consists essentially of alanine, glutamic acid, tyrosine and lysine, *and* a process for determining the average molecular weight of an aqueous mixture of polypeptides are being acted upon in this Office Action.

4. The abstract of the disclosure is objected to because it is more than one paragraph. Correction is required. See MPEP § 608.01(b). Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally *limited to a single paragraph* on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

5. Applicant should amend the first line of the specification to update the relationship between the instant application and 09/816,989 filed March 23, 2001, which is now Pat 6,800,287.

6. The reference pending claims of USSN 09/816,989 on PTO 1449, filed 3/2/04 has been considered but crossed out because pending claim is inappropriate for an IDS.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 123, 134, 145 and 155 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps in claims 123, 134, 145 and 155 are: the defined average molecular weight of the polypeptides, the amino acid sequences of the polypeptides, the desired molecular weight of the polypeptides/markers to be included in the pharmaceutical product for the claimed process.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 123-125, 127-128, 133-136, 138-139, 145-147, 149-150, 155-157 and 159-160 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat 5,800,808 (Sept 1, 1998; PTO 1449) as evident by the Pharmacia Biotech Directory (page 340-341, 1996; PTO 892).

The '808 patent teaches a process for obtaining a pharmaceutical product containing an aqueous mixture of polypeptides each of which consists of essentially of alanine, glutamic acid,

tyrosine and lysine wherein the reference mixture has a desired average molecular weight of about 4,000-8,600 Dalton which is within the claimed average molecular weight from 4000 to 13,000 Daltons (see col. 2, lines 8-14, in particular). During the process, a batch of the reference aqueous mixture of polypeptides is chromatograph on a column to such as Fractogel TSK and Superose 12 column (see col. 3, line 6-8, in particular) to establish a relationship between retention time on the column and the molecular weight (see paragraph bridging cols 2-3, in particular). The reference superpose 12 column inherently comprises a cross-linked agarose-based medium, with an exclusion limit of 2×10^6 Daltons, an optimal separation range of 1000 to $3x\ 10^5$ Daltons and a bead diameter of 20-40 μm based on average molecular weight of the reference 4,000-8,600 Daltons which is within the claimed average molecular weight from 4000 to 13,000 Daltons and as evident by evidentiary reference Pharmacia Biotech Directory (page 341, in particular). The reference process of obtaining the reference pharmaceutical product is by column chromatography of L-GLAT to obtain the desired average of molecular weight species (see Summary of invention, in particular).

11. Claims 123-125, 133-136 and 144 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat 5,858,964 (filed April 1995; PTO 1449).

The '964 patent teaches a process for obtaining a pharmaceutical product containing an aqueous mixture of polypeptides each of which consists of essentially of alanine, glutamic acid, tyrosine and lysine wherein the reference mixture has a desired average molecular weight of about 4,000-12,000 which is within the claimed average molecular weight from 4000 to 13,000 Daltons (see Summary of invention, col. 3, line 1-4, in particular). The reference process of obtaining the reference pharmaceutical product is by column chromatography of L-GLAT to obtain the desired average of molecular weight species (see col. 4, line 8-10, in particular). The step of calibrating the molecular weight obtained using the column chromatography is inherent in the reference process given that the reference method produces the same desire molecular weight. The reference polypeptide is copolymer-1, which is also known as glatiramer acetate (see col. 2, lines 18-21, in particular). The reference process further comprises a step of lyophilized the reference glatiramer acetate (see col. 4, line 35-36, in particular). Thus, the reference teachings anticipate the claimed invention.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 123, 127-128, 134, 138-139, 145, 149-150, 155, and 159-160 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat 5,858,964 (filed April 1995; PTO 1449) in view of Pharmacia Biotech Directory (page 340-341, 1996; PTO 892).

The teachings of the '964 patent have been discussed supra.

The invention in claims 127, 138, 149 and 159 and differs from the teachings of the references only in that the process for obtaining a pharmaceutical product wherein the gel permeation chromatography column comprises a cross-linked agarose-based medium, with an exclusion limit of 2×10^6 Daltons, an optimal separation range of 1000 to $3x\ 10^5$ Daltons and a bead diameter of 20-40 μm.

The invention in claims 128, 139, 150, and 160 differs from the teachings of the references only in that the process for obtaining a pharmaceutical product wherein the gel permeation chromatography column is Superose 12.

The Pharmacia Biotech directory teaches a process of separating peptide based on sized using Superose column such as Superose 12 that is a media that provides high resolution gel filtration at rapid flow rates in a wide range of buffer conditions (see page 340, col. 1, in particular). The reference gel permeation chromatography column comprises a cross-linked agarose-based medium with an exclusion limit of 2×10^6 Daltons, an optimal separation range of 1000 to $3x\ 10^5$ Daltons and a bead diameter of 20-40 μm (see page 341, far right col., in

particular). The reference further teaches that the highly cross-linked agarose structure of Superose is suitable for separation, purification and molecular weight determination of proteins, peptides and nucleic acid (see page 340, col. 1, first paragraph, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the chromatography column as taught by the '964 patent for the Superose column as taught by the Pharmacia Biotech directory for a method of obtaining a pharmaceutical product based on size exclusion as taught by the '964 patent and the Pharmacia Biotech directory. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the Pharmacia Biotech directory teaches that the highly cross-linked agarose structure of Superose is suitable for separation, purification and molecular weight determination of proteins, peptides and nucleic acid (see page 340, col. 1, first paragraph, in particular). The '964 patent teaches the desired average of molecular weight of copolymer-1 or glatiramer acetate that consists of essentially of alanine, glutamic acid, tyrosine and lysine as a pharmaceutical product is about 4,000-12,000 which is within the claimed average molecular weight from 4000 to 13,000 Daltons (see Summary of invention, col. 3, line 1-4, in particular).

15. Claims 126, 129-132, 137, 140-143, 148, 151-154, 158, and 161-164 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

18. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
December 22, 2004

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600